CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 040186

Trade Name : MEPERIDINE HYDROCHLORIDE TABLETS USP

Generic Name: Meperidine Hydrochloride Tablets USP, 50mg and 100mg

Sponsor : Royce Laboratories, Inc.

Approval Date: June 30, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 040186

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Pharmacology Review(s)				
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Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)	X			
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Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 040186

APPROVAL LETTER

ANDA 40-186

JUN 30 1997

Royce Laboratories, Inc.
Attention: William Stahovec
16600 NW 54th Ave.
Miami, FL 33014

Dear Sir:

This is in reference to your abbreviated new drug application dated March 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg.

Reference is also made to your amendments dated November 26, 1996, May 12 and 20, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Demerol® Tablets, 50 mg and 100 mg, respectively, of Sanofi Winthrop Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

(b)4 - Confidential 6/30/97

Douglas L. Spörn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

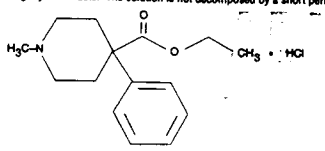
APPLICATION NUMBER 040186

FINAL PRINTED LABELING

Meperidine Hydrochloride Tablets, USP

DESCRIPTION

Meperidine hydrochloride is ethyl 1-methyl-4-phenylisonipecotate hydrochloride, a white crystalline substance with a melting point of 186°C to 189°C. It is readily soluble in water and has a neutral reaction and a slightly bitter taste. The solution is not decomposed by a short period of boiling. Its structure is as follows:



$C_{15}H_{21}NO_2 \cdot HCl$

Molecular Weight 283.80

Each tablet for oral administration contains 50 mg or 100 mg of meperidine hydrochloride. They are white, unscored, round, biconvex tablets. In addition, each tablet contains the following inactive ingredients: confectioners sugar, lactose monohydrate, magnesium stearate, povidone and sodium starch glycolate.

CLINICAL PHARMACOLOGY

Meperidine hydrochloride is a narcotic analgesic with multiple actions qualitatively similar to those of morphine; the most prominent of these involve the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value are analgesia and sedation.

There is some evidence which suggests that meperidine may produce less smooth muscle spasm, constipation, and depression of the cough reflex than equianalgesic doses of morphine. Meperidine, in 50 mg to 80 mg parenteral doses, is approximately equivalent in analgesic effect to 10 mg of morphine. The onset of action is slightly more rapid than with morphine, and the duration of action is slightly shorter. Meperidine is significantly less effective by the oral than by the parenteral route, but the exact ratio of oral to parenteral effectiveness is unknown.

JUN 30 1997

INDICATIONS AND USAGE

Meperidine hydrochloride tablets are indicated for the relief of moderate to severe pain.

CONTRAINDICATIONS

Hypersensitivity to meperidine.

Meperidine is contraindicated in patients who are receiving monoamine oxidase (MAO) inhibitors or those who have recently received such agents. Therapeutic doses of meperidine have occasionally precipitated unpredictable, severe, and occasionally fatal reactions in patients who have received such agents within 14 days. The mechanism of these reactions is unclear, but may be related to a preexisting hyperphenylalaninemia. Some have been characterized by coma, severe respiratory depression, cyanosis, and hypotension, and have resembled the syndrome of acute narcotic overdose. In other reactions the predominant manifestations have been hyperexcitability, convulsions, tachycardia, hyperpyrexia, and hypertension. Although it is not known that other narcotics are free of the risk of such reactions, virtually all of the reported reactions have occurred with meperidine. If a narcotic is needed in such patients, a sensitivity test should be performed in which repeated, small, incremental doses of morphine are administered over the course of several hours while the patient's condition and vital signs are under careful observation. (Intravenous hydrocortisone or prednisolone have been used to treat severe reactions, with the addition of intravenous chlorpromazine in those cases exhibiting hypertension and hyperpyrexia. The usefulness and safety of narcotic antagonists in the treatment of these reactions is unknown.)

WARNINGS

DRUG DEPENDENCE

Meperidine can produce drug dependence of the morphine type and therefore has the potential for being abused. Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of meperidine, and it should be prescribed and administered with the same degree of caution appropriate to the use of morphine. Like other narcotics, meperidine is subject to the provisions of the Federal narcotic laws.

INTERACTION WITH OTHER CENTRAL NERVOUS SYSTEM DEPRESSANTS

MEPERIDINE SHOULD BE USED WITH GREAT CAUTION AND IN REDUCED DOSAGE IN PATIENTS WHO ARE CONCURRENTLY RECEIVING OTHER NARCOTIC ANALGESICS, GENERAL ANESTHETICS, PHENOTHIAZINES, OTHER TRANQUILIZERS (SEE **DOSAGE AND ADMINISTRATION**), SEDATIVE-HYPNOTICS (INCLUDING BARBITURATES), TRICYCLIC ANTIDEPRESSANTS, AND OTHER CNS DEPRESSANTS (INCLUDING ALCOHOL). RESPIRATORY DEPRESSION, HYPOTENSION, AND PROFOUND SEDATION OR COMA MAY RESULT.

HEAD INJURY AND INCREASED INTRACRANIAL PRESSURE

The respiratory depressant effects of meperidine and its capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a preexisting increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries. In such patients, meperidine must be used with extreme caution and only if its use is deemed essential.

ASTHMA AND OTHER RESPIRATORY CONDITIONS

Meperidine should be used with extreme caution in patients having an acute asthmatic attack, patients with chronic obstructive pulmonary disease or cor pulmonale, patients having a substantially decreased respiratory reserve, and patients with preexisting respiratory depression, hypoxia, or hypercapnia. In such patients, even usual therapeutic doses of narcotics may decrease respiratory drive while simultaneously increasing airway resistance to the point of apnea.

HYPOTENSIVE EFFECT

The administration of meperidine may result in severe hypotension in the postoperative patient or any individual whose ability to maintain blood pressure has been compromised by a depleted blood volume or the administration of drugs such as the phenothiazines or certain anesthetics.

USAGE IN AMBULATORY PATIENTS

Meperidine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient should be cautioned accordingly.

Meperidine, like other narcotics, may produce orthostatic hypotension in ambulatory patients.

USAGE IN PREGNANCY AND LACTATION

Meperidine should not be used in pregnant women prior to the labor period, unless in the judgment of the physician the potential benefits outweigh the possible hazards, because safe use in pregnancy prior to labor has not been established relative to possible adverse effects on fetal development.

Meperidine appears in the milk of nursing mothers receiving the drug.

PRECAUTIONS

SUPRAVENTRICULAR TACHYCARDIAS

Meperidine should be used with caution in patients with atrial flutter and other supraventricular tachycardias because of a possible vagolytic action which may produce a significant increase in the ventricular response rate.

CONVULSIONS

Meperidine may aggravate preexisting convulsions in patients with convulsive disorders. If dosage is escalated substantially above recommended levels because of tolerance development, convulsions may occur in individuals without a history of convulsive disorders.

ACUTE ABDOMINAL CONDITIONS

The administration of meperidine or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

SPECIAL RISK PATIENTS

Meperidine should be given with caution and the initial dose should be reduced in certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

ADVERSE REACTIONS

The major hazards of meperidine, as with other narcotic analgesics, are respiratory depression and, to a lesser degree, circulatory depression; respiratory arrest, shock, and cardiac arrest have occurred.

The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea, vomiting, and sweating. These effects seem to be more prominent in ambulatory patients and in those who are not experiencing severe pain. In such individuals, lower doses are advisable. Some adverse reactions in ambulatory patients may be alleviated if the patient lies down.

Other adverse reactions include:

NERVOUS SYSTEM

Euphoria, dysphoria, weakness, headache, agitation, tremor, uncoordinated muscle movements, transient hallucinations and disorientation, visual disturbances.

GASTROINTESTINAL

Dry mouth, constipation, biliary tract spasm.

CARDIOVASCULAR

Flushing of the face, tachycardia, bradycardia, palpitation, hypotension (see WARNINGS), syncope.

GENITOURINARY

Urinary retention.

ALLERGIC

Pruritus, urticaria, other skin rashes.

OTHER

Antidiuretic effect.

OVERDOSAGE

SYMPTOMS

Serious overdosage with meperidine is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, particularly by the intravenous route, apnea, circulatory collapse, cardiac arrest, and death may occur.

TREATMENT

Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and institution of assisted or controlled ventilation. The narcotic antagonist, naloxone hydrochloride, is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including meperidine. Therefore, an appropriate dose of this antagonist should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression.

Oxygen, intravenous fluid, vasopressors, and other supportive measures should be employed as indicated.

In cases of overdosage with meperidine the stomach should be evacuated by emesis or gastric lavage.

NOTE: In an individual physically dependent on narcotics, the administration of the usual dose of a narcotic antagonist will precipitate an acute withdrawal syndrome. The severity of this syndrome will depend on the degree of physical dependence and the dose of antagonist administered. The use of narcotic antagonists in such individuals should be avoided if possible. If a narcotic antagonist must be used to treat serious respiratory depression in the physically dependent patient, the antagonist should be administered with extreme care and only one-fifth to one-tenth the usual initial dose administered.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted according to the severity of the pain and the response of the patient. Meperidine is less effective orally than on parenteral administration. The dose of meperidine hydrochloride should be proportionately reduced (usually by 25 to 50 percent) when administered concomitantly with phenothiazines and many other tranquilizers since they potentiate the action of meperidine.

ADULTS

The usual dosage is 50 mg to 150 mg orally, every 3 or 4 hours as necessary.

CHILDREN

The usual dosage is 0.5 mg/lb to 0.8 mg/lb orally up to the adult dose, every 3 or 4 hours as necessary.

HOW SUPPLIED

Meperidine hydrochloride tablets, USP, 50 mg are white, round, unscored, biconvex compressed tablets, debossed 409 over 50 on one side and the Royce Logo on the other side.

Size	Royce NDC Number
100	51875-0409-1
500	51875-0409-2
1000	51875-0409-4

Meperidine hydrochloride tablets, USP, 100 mg are white, round, unscored, biconvex compressed tablets, debossed 410 over 100 on one side and the Royce Logo on the other side.

Size	Royce NDC Number
100	51875-0410-1
500	51875-0410-2
1000	51875-0410-4

Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Caution: Federal law prohibits dispensing without prescription.

Manufactured by
Royce Laboratories, Inc
16600 N.W. 54 Avenue
Miami, FL 33014

Issued 05/97

NDC 51875-0409-1

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

CAUTION: Federal law prohibits dispensing without prescription.

100 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 50 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0409-1 3

NDC 51875-0410-1

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

100 mg

CAUTION: Federal law prohibits dispensing without prescription.

100 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 100 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0410-1 9

NDC 51875-0409-2

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

CAUTION: Federal law prohibits dispensing without prescription.

500 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 50 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0409-2 0

NDC 51875-0410-2

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

100 mg

CAUTION: Federal law prohibits dispensing without prescription.

500 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 100 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0410-2 6

NDC 51875-0409-4

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

CAUTION: Federal law prohibits dispensing without prescription.

1000 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 50 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0409-4 4

NDC 51875-0410-4

Royce™

MEPERIDINE HYDROCHLORIDE TABLETS, USP

C II

WARNING: May be habit forming

100 mg

CAUTION: Federal law prohibits dispensing without prescription.

1000 Tablets

Mfd. By: Royce Laboratories, Inc., Miami, FL 33014

Each tablet contains:
Meperidine Hydrochloride, USP ..... 100 mg

Usual Dosage: See package insert for complete prescribing information.

Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in a tight, light-resistant container as defined in the USP.

Batch No.:

Exp. Date: JUN 30 1997

N 3 51875-0410-4 0

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 040186

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-186

3. NAME AND ADDRESS OF APPLICANT
Royce Laboratories
Attention: William Stahovec
16600 NW 54th Avenue
Miami, FL 33014

4. BASIS OF SUBMISSION
The applicant certifies that to the best of their knowledge there are no unexpired patents or exclusivities for Meperidine Hydrochloride Tablets, USP.

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME

7. NONPROPRIETARY NAME
Meperidine Hydrochloride Tablets USP

8. SUPPLEMENT PROVIDE FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
March 29, 1996-- Original Submission
July 10, 1996-- Bio Review--Satisfactory
July 15, 1996-- Bio letter to firm
July 31, 1996-- Labeling review
September 30, 1996--Deficiency letter
November 26, 1996-- Amendment

10. PHARMACOLOGICAL CATEGORY
Narcotic Analgesic

11. Rx or OTC
Rx

12. RELATED Drug Master Files

ide

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(b)4 - Confidential Business

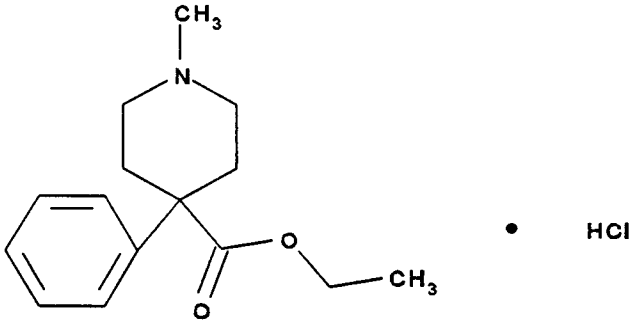
13. DOSAGE FORM
Tablets

14. POTENCY
50 mg & 100 mg

15. CHEMICAL NAME AND STRUCTURE

Meperidine Hydrochloride USP

$C_{15}H_{21}NO_2.HCl$; M.W. = 283.80



Ethyl 1-methyl-4-phenylisonipecotate hydrochloride.
CAS [50-13-5]

16. RECORDS AND REPORTS

N/A

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend approval letter to issue. Labeling review was found acceptable, dated 5/9/97. Pending EER update results.

19. REVIEWER: Edwin Ramos

/S/

DATE COMPLETED: April 27, 1997

6/26/97

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 040186

BIOEQUIVALENCE REVIEW(S)

ANDA 40-186

JUL 15 1996

Royce Laboratories, Inc.
Attention: Loren Gelber, Ph.D.
16600 NW 54th Avenue
Miami FL 33014

Dear Madam:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Meperidine Hydrochloride Tablets USP, 50 mg and 100 mg.

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

/S/

Keith K. Chan, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

JUL 10 1996

Meperidine Hydrochloride
50 and 100 mg Tablets
ANDA #40-186
Reviewer: Jahnavi S. Kharidia
x:\jsk\40186w.s96

Royce Laboratories, Inc.
16600 NW 54 Avenue
Miami, FL 33014
Submission Date:
~~April 4, 1996~~
March 29, 1996

Review of Dissolution Data and Two Waiver Request

Introduction:

Meperidine hydrochloride is a narcotic analgesic. The principal actions of therapeutic value are analgesia and sedation.

Objective:

The firm has submitted an application for two strengths of meperidine hydrochloride tablets and has requested waivers for *in vivo* bioequivalence testing requirements based on the fact that meperidine hydrochloride tablets, USP are rated AA in the Orange Book. The firm has conducted dissolution testing on the two strengths of the test products and the corresponding two strengths of Demerol® tablets, Winthrop Pharmaceuticals.

Comments:

1. The firm has submitted comparative *in vitro* dissolution data on meperidine hydrochloride tablets (50 mg and 100 mg) and the listed reference product, Demerol® tablets (50 mg and 100 mg). The dissolution was conducted using the USP dissolution parameters and the dissolution samples were analyzed by two different methods: (a) by UV method described in USP and (b) by HPLC method described in USP for the assay samples.

2. The current official UV method (a) has been reported to introduce significant analytical variability into the results. In the recent Pharmacopeial Forum (Vol. 22, Number 2, p.2131), it has been suggested that analysis of dissolution samples by HPLC is preferable to analysis by UV method.

3. The dissolution data obtained from the both methods (UV and HPLC) show that at the 10 minute sampling interval the test products are completely dissolved, while the Demerol® tablets are not dissolved until the 30 minute sampling time. Both

products, however, met the agency specification of:

Not less than (b)4 of the labeled amount of the meperidine hydrochloride in the tablet is dissolved in 45 minutes.

4. The formulations of meperidine hydrochloride 50 mg and 100 mg tablets are identically proportionate.

5. The firm intends to use in-house (b)4 - method for routine analysis of the test product. The firm has provided additional dissolution data at 45 minute using this in-house method and these data are acceptable.

Recommendation:

1. The Division of Bioequivalence agrees that the information submitted by Royce Laboratories demonstrates that meperidine hydrochloride 50 mg and 100 mg tablets falls under 21 CFR Section 320.22 (C) of the Bioavailability / Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of an *in vivo* bioequivalence study be granted. Royce's meperidine hydrochloride 50 mg and 100 mg tablets are deemed bioequivalent to Demerol® 50 mg and 100 mg tablets, respectively, manufactured by Winthrop Pharmaceuticals.

2. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution testing should be conducted in 500 mL of water at 37° C using USP XXIII Apparatus I (basket) at 100 RPM. The test should meet the following specification:

   Not less than (b)4 of the labeled amount of the drug in the tablet is dissolved in 45 minutes.

3. The firm should be informed of the recommendations.

/S/

J. S. Kharidia, Ph.D.
Division of Bioequivalence
Review Branch III

RD Initialed R.M. Mhatre
FT Initialed R.M. Mhatre

/S/ Date: 7/8/96

Ramakant M. Mhatre, Ph.D.

Table 1: Dissolution Parameters And Results

Apparatus: USP XXIII Apparatus I (basket) at 100 RPM

Medium: 500 mL Water at 37° C

Method of Assay: A - HPLC, USP
B - UV, USP

Specifications: NLT [redacted](b)4Q) in 45 minutes for active ingredient

Test product: Meperidine Hydrochloride 50 mg Tablets, lot #: MG-1451
Meperidine Hydrochloride 100 mg tablets, lot #: MG-1457

Approved product: Demerol® 50 mg and 100 mg Tablets, lot # NA401 and # NB395, respectively

Method A - HPLC, USP

Strength	Time (minute)	Test Product Mean % Dissolved	Test Product CV%	Reference Product Mean % Dissolved	Reference Product CV%
50 mg	10	102.0	1.6	98.2	6.2
	20	102.1	1.3	105.1	2.6
	30	101.2	1.4	104.6	2.3
	45	101.2	1.4	105.9	2.7
	60	100.3	1.4	105.2	2.7
100 mg	10	100.9	1.3	80.4	4.3
	20	102.0	1.1	103.8	2.2
	30	102.0	1.1	103.8	2.2
	45	102.0	1.2	103.7	2.2
	60	102.1	1.1	103.9	2.0

Method B - UV, USP

Strength	Time (minute)	Test Product		Reference Product	
		Mean % Dissolved	CV%	Mean % Dissolved	CV%
50 mg	10	95.6	4.2	89.5	9.3
	20	94.0	7.0	92.8	6.4
	30	94.5	3.6	93.9	3.3
	45	92.6	5.9	92.7	6.2
	60	93.8	3.2	89.3	8.4
100 mg	10	97.6	1.8	79.3	3.8
	20	99.0	1.4	100.6	1.6
	30	99.3	1.0	100.6	2.6
	45	99.3	2.6	100.5	3.5
	60	99.1	1.4	102.0	1.8

Formulation of Royce Laboratories' Meperidine Hydrochloride Tablets, USP 50 mg and 100 mg

Ingredients (mg)	Meperidine 50 mg tablet	Meperidine 100 mg tablet
Meperidine Hydrochloride, USP	50.0	100.0
Confectioners Sugar, NF	(b)4 - Confidential Business	
Lactose Monohydrate, NF		
Povidone, USP		
Sodium Starch Glycolate, NF		
Magnesium Stearate, NF		
Total Weight (mg)	150.0	300.0